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### **REMARKS/ARGUMENTS**

Favorable reconsideration of this application is requested in view of the amendments above and the remarks below.

#### **Disposition of Claims**

Claims 12-15, 17, 18, and 24 are pending in this application.

#### **Rejections under 35 U.S.C. §103**

A. Claims 12-15, 17, 18, and 24 were rejected under 35 U.S.C. §103(a) as being obvious over Wong et al. (U.S. Patent No. 5,324,280). Reconsideration of this rejection is respectfully requested.

Amended claim 12 recites a sustained-release dosage form for the delivery of a progestogenic steroid. The dosage form comprises a capsule and a self-emulsifying drug formulation contained within a first portion of the capsule, wherein the self-emulsifying drug formulation comprises a progestogenic steroid. The dosage form further comprises an expandable layer contained within a second portion of the capsule, wherein the expandable layer is positioned such that the self-emulsifying drug formulation can be expelled from the capsule upon expansion of the expandable layer. The dosage form further comprises a semipermeable membrane formed over at least a portion of an outer surface of the capsule.

Wong et al. teach an osmotic dosage form wherein a drug formulation is contained within a capsule. The capsule itself is encapsulated within a hydro-activated layer. Thus the interface between the drug formulation and the hydro-activated layer has a large surface area (i.e., equal to the surface area of the capsule containing the drug formulation). For an oily drug formulation, significant mixing between the drug formulation and the hydro-activated layer when hydrated is not expected. However, if the drug formulation is self-emulsifying, there will be significant mixing between the drug formulation and the hydro-activated layer, which would lead to erratic release profile of the drug and a very high amount of drug residue after release.

In claim 12, the self-emulsifying drug formulation is contained within a first portion of the capsule and the expandable layer is contained within a second portion of the capsule. Thus both the self-emulsifying drug formulation and the expandable layer are contained within the

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same capsule, and the expandable layer does not encapsulate the drug formulation. In contrast to the Wong et al. system where the hydro-activated layer encapsulates the capsule containing the drug formulation, the surface area at the interface between the drug formulation and the expandable layer recited in claim 12 is small. This small surface area eliminates or minimizes undesirable mixing between the drug formulation and the expandable layer, especially after hydration.

From the foregoing, it is clear that claim 12 is not obvious over Wong et al. Withdrawal of the obviousness rejection of claim 12 over Wong et al. is respectfully requested. Claims 13-15, 17, 18, and 24, which depend from claim 12, are likewise patentable over Wong et al. in view of the foregoing arguments. Withdrawal of the rejection of these claims is also respectfully requested.

B. Claims 12-15, 17, 18, and 24 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lambert et al. (U.S. Patent No. 6,458,373) in view of Wong et al. (U.S. Patent No. 5,324,280). Reconsideration of this rejection is respectfully requested.

Lambert et al. teach an  $\alpha$ -tocopherol emulsion in the form of a self-emulsifying system encapsulated in a soft or hard gelatin capsule. Lambert et al. do not teach or disclose that an expandable layer is also contained within the capsule. In contrast, claim 12 recites a self-emulsifying drug formulation and an expandable layer contained within the same capsule. This allows controlled release of the drug as well as minimizes undesirable mixing between the drug formulation and the expandable layer. Wong et al., which has been discussed above, fail to overcome the deficiencies in Lambert et al. Therefore, claim 12 cannot be obvious over Lambert et al. in view of Wong et al. Withdrawal of the rejection of claim 12 is respectfully requested. Claims 13-15, 17, 18, and 24, which depend from claim 12, are likewise patentable over the combination of Lambert et al. and Wong et al. Withdrawal of the rejection of these claims is also respectfully requested.

### Conclusion

The rejected claims have been amended and/or shown to be allowable over the prior art. Applicant believes that this paper is fully responsive to each and every ground of rejection cited

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by the Examiner in the Office Action dated June 15, 2004, and respectfully requests that a timely Notice of Allowance be issued in this case.

Please apply any charges or credits in connection with this filing to Deposit Account No. 50-3202 (Docket No. ARC 2556N1).

Respectfully submitted,

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